a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body; and

a plurality of suction ports located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, wherein at least one of the plurality of suction ports is disposed between each pair of heating elements, whereby suction applied to the vessel through the plurality of suction ports will draw the tissue of the vessel near each of the plurality of valves toward each pair of heating elements; and

a vacuum source operably connected to the suction lumen.

Remarks

Claims 1-5, 9 and 10 remain pending in the application.

Applicant believes that the amendments to the claims will place the application in condition for allowance. Thus, Applicant requests that the Examiner enter this after-final amendment and allow the claims.

Applicant has amended independent claims 1, 9 and 10 to include a vacuum source operably connected to the suction lumen. The vacuum source is not shown in the art cited by the Office Action.

The Office Action rejects claims 1 through 5 as anticipated by Swartz et al., Process and Device for the Treatment of Atrial Arrhythmia, U.S. Patent 5,938,660 (Aug. 17, 1999) under the assertion that Swartz discloses a device having a catheter body, a first and second balloons, a heating element, a suction lumen having a suction port, and different sources of energy used for catheter ablation such as direct current and RF energy.

Swartz does not disclose a vacuum source. Thus, Swartz does not anticipate claims 1-5, 9 or 10. Swartz also does not suggest a vacuum source since Swartz does not use suction to draw tissue near a valve toward his RF electrode. Instead, Swartz introduces a conductive media into the space between his two balloons and then applies RF energy to the conductive media to ablate a heart blood vessel. Indeed, the Swartz device will not repair valves since Swartz does not attempt shrink the lumen he seeks to ablate, and Swartz provides no mechanism or feature for doing so. On the other hand, Applicant's claims include a vacuum source that, when in use with the device, will cause tissue to come in contact with the electrodes.

The Office Action rejects claims 1-5 and 9-10 as anticipated by Ramsey, III, Esophageal Catheters and Method of Use, U.S. Patent 6,148,222 (Nov. 14, 2000) under the assertion that Ramsey discloses a device having a catheter body, a first and second balloon located at the distal end of the catheter, a first and second heating element and wires. The Office Action also asserts that Ramsey shows a plurality of balloons, a plurality of suction lumens and a plurality of heating elements and wires.

Ramsey does not disclose a vacuum source. Thus, Ramsey does not anticipate claims 1-5, 9 or 10. In addition, Ramsey does not disclose a heating element (or, in reference to claim 4, a resistive heating element). Ramsey does show electrodes for propagating a current into the body, but he specifically avoids heating of any kind. Accordingly, the Ramsey electrodes do not comprise heating elements. Thus, again, Ramsey does not anticipate claims 1-5, 9 and 10.

Ramsey also does not suggest a vacuum source, since Ramsey does not use suction to draw tissue toward his electrodes. Instead, Ramsey introduces a conductive media into the space between his balloons and then applies electrical energy to defibrillate the heart. Indeed, Ramsey specifically teaches away

from the claims since he specifically seeks to avoid ablating the esophagus. Ramsey would certainly never add any device to a lumen that would result in drawing the tissue of the esophagus towards his electrode, because his device is not intended to thermally damage any part of the esophagus, and doing so would be contradictory to the several features he mentions which are intended to protect the esophagus. Thus, Ramsey does not suggest claims 1-5, 9 and 10.

The Office Action rejects claims 4 and 5 as obvious over Swartz in view of Laufer et al., Method of Treating a Bronchial Tube with a Bronchial Stenter Having Diametrically Adjustable Electrodes, U.S. Patent 6,283,989 (Sep. 24, 2001) under the assertion that Swartz discloses the claimed invention and that Laufer teaches electrodes for delivering heat from an RF energy supply, and that it would have been obvious to combine the two.

First, regarding claim 4, the rejection ignores the limitation to the resistive heating element. Second, Applicant has added limitation to a vacuum source so it is not possible to combine the references to meet the claimed inventions. There is no suggestion to add a vacuum source to either Swartz or Laufer. Accordingly, claims 1-5, 9 and 10 are not obvious in view of Swartz and Laufer.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. Entry of this amendment is requested. Reconsideration of the rejections and allowance of the claims is also requested.

Date: December 23, 2002 By: Theodore D. Fay III

Theodore D. Fay III, Esq.
Reg. No. 48,504

Docket No. 212/262

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:	
Mollenauer	Art Unit: 3763
Serial No.: 09/598,852	
Filed: June 20, 2000	
For: Devices and Methods for Repair of Valves in the Human Body	Examiner: Thanh, L.

ATTACHMENT OF CLAIMS AND AMENDED SPECIFICATION PARAGRAPHS

The claims, including those amended by the Response submitted herewith on December 23, 2002, are as follows:

1. (amended) A device for treating an incompetent anatomical valve or sphincter within the body of a patient, wherein said valve or sphincter controls flow of fluid through a vessel of the body and is supported by tissue of the vessel near the valve, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body;

a heating element mounted on the distal end of the catheter, proximal to the first balloon;

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, and a suction port located on the distal end of the catheter communicating from suction lumen to the exterior of the catheter body, said suction port being located proximal the heating element; whereby suction applied to the vessel through the suction port will draw the tissue of the vessel near the valve toward the heating element; and

a vacuum source operably connected to the suction lumen.

2. (unchanged) The device of claim 1 further comprising:

a second balloon located at the distal end of the catheter, proximal to the first balloon, the heating element and suction port, said second balloon being inflatable to a diameter greater than the catheter body distal end.

3. (unchanged) The device of claim 2 further comprising:

a second inflation lumen communicating from the proximal end of the catheter body to the second balloon on the distal end of the catheter body.

4. (unchanged) The device of claim 1 further comprising:

a pair of wires running from the heating element to the proximal end of the catheter, said wires adapted to electrically connect the heating element to direct current power supply; and

wherein the heating element is a resistive heating element.

5. (unchanged) The device of claim 1 further comprising:

a wire running from the heating element to the proximal end of the catheter, said wire adapted to electrically connect the heating element to a radiofrequency power supply; and

wherein the heating element is a radiofrequency electrode adapted for transmission of radiofrequency energy into the tissue of the vessel.

9. (amended) A device for treating an incompetent anatomical valve or sphincter within the body of a patient, wherein said valve or sphincter controls flow of fluid through a vessel of the body and is supported by tissue of the vessel near the valve, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the first inflation lumen is in fluid communication with the first balloon;

a first heating element mounted on the distal end of the catheter, proximal to the first balloon;

a second balloon located at the distal end of the catheter, said second balloon being inflatable to a diameter greater than the catheter body distal end, said second balloon proximal to the first balloon and proximal to the first heating element, and a second inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the second inflation lumen is in fluid communication with the second balloon;

a second heating element mounted on the distal end of the catheter, distal to the second balloon and proximal to the first heating element;

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, and at least one suction port located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, said at least one suction port being located proximal to the first heating element and distal to the second heating element; whereby suction applied to the vessel through the at least one suction port will draw the tissue of the vessel near the valve toward the first and second heating elements; and

a vacuum source operably connected to the suction lumen.

10. (amended) A device for treating a plurality of incompetent anatomical valves or sphincters within the body of a patient, wherein said plurality of valves or sphincters control flow of fluid through a vessel of the body and are supported by tissue of the vessel near the plurality of valves, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the first inflation lumen is in fluid communication with the first balloon;

a second balloon located at the distal end of the catheter, said second balloon being inflatable to a diameter greater than the catheter body distal end, said second balloon proximal to the first balloon, and a second inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the second

inflation lumen is in fluid communication with the second balloon;

a plurality of heating elements mounted on the distal end of the catheter body, wherein each of the plurality of heating elements are disposed in series along the length of the catheter body, wherein two succeeding heating elements comprise a pair of heating elements, and wherein the pair of heating elements are further disposed on the catheter body such that a section of catheter body separates each pair of heating elements; and

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body; and

a plurality of suction ports located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, wherein at least one of the plurality of suction ports is disposed between each pair of heating elements, whereby suction applied to the vessel through the plurality of suction ports will draw the tissue of the vessel near each of the plurality of valves toward each pair of heating elements; and

a vacuum source operably connected to the suction lumen.

End